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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,179	07/30/2001	Klaus Draenert	ZIP 2296	2627

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EXAMINER

ROBERT, EDUARDO C

ART UNIT PAPER NUMBER

3732

DATE MAILED: 08/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,179

Applicant(s)

DRAENERT, KLAUS

Examiner

Eduardo C. Robert

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 16-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 16-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

The drawings are objected to because the Figures are not labeled, .e.g. Figure 1, Figure 2, etc. Also, they contain extraneous matter, e.g. "Abb 01", "Schnitt", etc., which is not permitted and should be removed. Correction is required.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Applicant is required to submit a proposed drawing correction in response to this Office Action. Any proposal by the applicant for amendment of the drawings to cure defects must consist of two parts:

- a) A separate letter to the Draftsman in accordance with MPEP § 608.02(r); and
- b) A print or pen-and-ink sketch showing changes in red ink in accordance with MPEP § 608.02(v).

IMPORTANT NOTE: The filing of new formal drawings to correct the noted defect may be deferred until the application is allowed by the examiner, but the print or pen-and-ink sketch with proposed corrections shown in red ink is required in response to this Office Action, and may not be deferred.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure. The specification appears to be a direct translation from a foreign document and the description of the invention is so unclear and confusing that one skilled in the art would not be able to make and/or use the invention. Moreover, the specification is confusing because almost each element identified in the specification and figures appear to be describing two different elements, e.g. reference number "100" directed to both an "axis" and "stem segments"; reference number "100.1" directed to both "base segment" and "methaphysical segment"; reference number "100.3" directed to both "base segment" and "stem segment"; etc., and thus one skilled in the art would not be able to make and/or use the invention. Another example of the poorly written description is on page 2, lines 24-37, which states: "The modular system essentially is comprises of an axis (100), which corresponds to a cylinder located around the medullary canal axis. Various segments must be used in sequence around this cylinder: the base segment

(100.1) may be of various lengths, and it is always comprised of the tip (102) and the axial cylinder (103)". Here, it is unclear how the various segments "must be used" around the cylinder which appear to be the one having an axis 100 which in the figures is shown as being composed of three different parts, so how various segments, i.e. base segment, etc., are used around the cylinder with axis 100 and having three different parts. It is noted that this is just one example of the many problems this specification have. Applicant is advised to re-write the specification so that the invention is properly described and reference numeral clearly identify an specific element of the invention. Also, elements in the list of reference numbers (pages 9 and 10) should correspond to the same elements in the specification and figures.

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). It is noted that there are numerous terms in the claims that do not have antecedent basis in the specification, examples are "dorsolateral cylindrical component", "a shaft cone transition", etc. Applicant is advised to review all the claims so that all the terms in the claims have proper antecedent basis.

The disclosure is objected to because of the following informalities: there is no brief description for the drawings. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1, 2, 16-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. (see rejection of specification above).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, and 16-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, and 16-28 are replete with errors too numerous to mention specifically. Example of such errors include: in claim 1, lines 3, 4, 6, 11, 12, terms, “the following elements”, “the stem”, “the intermedullary canal”, “the proximal metaphysial component”, “the cone”, “the central or eccentric head” each lacks a prior antecedent. Moreover, in the same claim 1, line 7, the terms or phrases “may be” and “can be” renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention or not, and the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Applicant is advised to carefully reread the claims and correct all errors found therein, including antecedent basis in the specification (see rejection above).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 16-28, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Kranz.

Kranz discloses a modular prosthesis similar to the one shown in applicant's figures.

Conclusion

A substitute specification including the claims is required pursuant to 37 CFR 1.125(a) because of the numerous problems the specification and claims have (see objections and rejection to the specification and claims above).

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

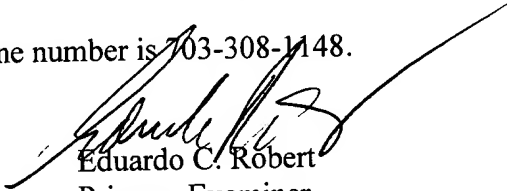
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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Richelsoph; Bresler, et al.; Lob, et al. ; Masini ; Fischer ; Pavlansky, et al. ; Chernoff ; Gie, et al. ; and Despres, III et al. are cited art of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 703-308-2698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C. Robert
August 23, 2002